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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,082	09/24/2001	Wei-Sing Chu	2313-113	1159
6449	7590	10/19/2005	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			CHUNDURU, SURYAPRABHA	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,082

Applicant(s)

CHU, WEI-SING

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-26,44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-26,44 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 04, 2005 has been entered.

Status of the Application

2. The action is in response to the RCE filed on August 04, 2005. Currently claims 20-26, 44 - 45 are pending. Claims 1-19, 27-43 are cancelled. New claim 45 is added. All arguments and amendment have been fully considered and thoroughly reviewed and deemed persuasive in part view of the amendment.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-26, 44-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims recite "predetermined volume", which is unclear or indefinite because the instant specification neither provides any definition for the predetermined volume nor does provide what volume is considered as predetermined volume. Therefore the meets and bounds of the claims are unclear. Further the claim 45 recites a range of

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volume between 10 ul and 20ul, which is unclear, as a predetermined volume should have a fixed volume, not a range of volumes as claimed.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claims 20, 22-23, 25, 44-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Atwood et al. (USPN 5,364,790).

Regarding Claim 20, Atwood teaches an apparatus comprising:

a microscope slide (see col. 7, line 37-38);

a cover slip having a concave well disposed on said slide (see col. 7, line 38-41. line 64-67, col. 8, line 1-3);

said concave well having a known volume wherein said concave well encloses said known volume when placed onto a microscope slide (see col. 7, line 66-67, col. 8, line 1-3, wherein volume about 10 microliters is a known volume that the concave well encloses when placed onto said slide, see also claim 4 on col.20).

Regarding Claims 22-23, Atwood teaches that the apparatus further comprises an insert (seal ring integral with cross beams) sandwiched between a portion of said cover slip and said

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microscope slide, that comprises sample (control sample) (*see* col. 8, line 37-67) col. 17, line 13-63);

Regarding Claim 25, 44, Atwood teaches a method and system for performing an assay (e.g., a PCR reaction) on a biological sample on a microscope slide, comprising, a) placing a biological sample on a microscope slide (*see* col. 6, line 5-9, col. 21, line 33-36); b) placing the cover slip of on said microscope slide (*see* col. 6, line 9-10, col. 21, line 38-39); allowing water, buffer or reagent to flow into the known volume between said microscope slide and said cover slip and allowing a reaction to occur (*see* col. 6, line 10-26, col. 21, line 40-48).

With regard to claim 45, Atwood et al. teach that said predetermine volume is about 10ul (*see* col. 8, line 1-3). Accordingly Atwood et al. anticipates the instant claims.

B. Claim 20, 22-23, 25, 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown et al. (USPN. 6, 143, 496).

Brown et al. teach an apparatus of claim 20 and a method of claim 25 for processing of a sample comprising;

(a) a microscope slide (*see* col. 15, line 9-19);

(b) a coverslip having a concave well (cavity) (*see* col. 15, line 9-19, col. 17 line 13-47, indicating first and second plates as microscope slide and coverslip having cavity to hold sample reagents); wherein said well having predetermined volume, when placed on a microscope slide (*see* col. 16, line 1-20).

With regard to claim 22-23, Brown et al. teach that said apparatus comprises an insert sandwiched between a portion of said coverslip and said microscope and said insert comprises a control sample (*see* col. 32, line 39-51);

With regard to claim 25, Brown et al. teach that the method comprises allowing sample reagent to flow into the cavity between cover slip and the microscope slid and allowing the reaction to occur (see col. 29, line 42-64);

With regard to claim 44, Brown et al. teach a system comprising a means for placing a biological sample on a microscope slide, means for providing a coverslip having a concave well of a predetermined volume, means for placing coverslip on said microscope slide, means for allowing water, buffer or reagent to flow into the well and means for allowing the reaction to occur (see col. 20, line 1-42). Accordingly Brown et al. anticipates the instant claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 21 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atwood et al. (USPN 5,364,790) in view of Pan et al. (WO 97/07241).

Atwood et al teach an apparatus and a method for processing of a sample as discussed above in section 4A.

However Atwood does not teach a cover slip comprising reagents dried thereon.

However, drying reagents onto cover slips is well known in the art. For example, Pan teaches a PCR reaction comprising attaching a tissue section onto a cover slip, drying the tissue, and then adding reagents to carry out the PCR reaction. See pages 3-10 and example 4. Pan teaches that the tissue can be attached to the cover slip, rinsed in alcohol and allowed to dry prior

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to PCR. *See* page 5. Pan also teaches that prior to the attachment of the tissue, the cover slip can have a pre-dried adhesive on the surface of the cover slip (page 9), or can simply be dried over night (page 18). Pan teaches the above methods provided a simplified method that is faster, more accurate and less expensive than previous methods of carrying out PCR. *See* pages 1-3.

Accordingly, in view of the teachings of Pan, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Atwood et al. so as to have dried reagents on a cover slip as taught by Pan et al., in order to achieve the benefit of providing a more efficient, accurate and less expensive method of carrying out PCR.

B. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Atwood et al. in view of Kuan et al. (USPN 6,181,811).

Atwood et al teach an apparatus and a method for processing of a sample as discussed above in section 4A.

Atwood et al. does not teach a cover slip comprising a barcode or text.

Kuan teaches that barcodes can be used for identification purposes in automated systems. *See* Figs. 8a and b and cols. 14-15.

Accordingly, in view of the teachings of Kuan, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the coverslip of Atwood so as to label the coverslip with a barcode or text taught by Kaun et al., in order to achieve the benefit of providing an effective means for identifying a sample in an automated system.

Response to Arguments:

6. With regard to the priority claim to US non-provisional 09/219, 443 Applicants' arguments are fully considered and found not persuasive. After a through review of Fig. 16A, 16B, 16D and example 9, Examiner notes that the use of a coverslip having a concave well is not present. The cited Figs and the example 9 discloses a tray with wells and does not disclose a coverslip having concave well and hence the arguments regarding the priority claim are not persuasive and the instant application gets the benefit of filing date as 12/22/1999.

7. With regard to the rejection under 35 USC 102(b) as anticipated by Atwood, Applicants' arguments and amendment are fully considered and found unpersuasive. Applicants' argue that the cover membrane taught by Atwood does not hold a predetermined volume as required by the instant claim 20 and the cover membrane expands and contracts like a tire or balloon accommodating any given volume of liquid or air rather than holding a predetermined volume. Applicants' arguments are fully considered and found unpersuasive. The instant claims broadly recites a cover slip having a concave well, which reads on any type of cover membrane or coverslip (flexible (expand or contract) or rigid type). Further the Atwood teaches fixed reagent volume without a large increase in pressure, which clearly indicate that a fixed or predetermined volume is applied to the coverslip or cover membrane. Applicants argue that the fixed volume has to be measured beforehand and is different from the instant invention in which the concave well itself has a predetermined volume. Applicants' arguments are fully considered and found unpersuasive because in order to have a predetermined volume in said concave well, one has to apply a pre-measured volume beforehand. Since the instant claims do not recite what exact

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volume indicates “predetermined volume”, the fixed volume taught by Atwood is considered as predetermined volume and therefore the rejection is maintained.

8. With regard to the rejection under 35 USC 103(a) as being obvious over Atwood in view of Pan et al., Applicants’ arguments and amendment are fully considered and found unpersuasive. As discussed above Atwood does teach a predetermined volume and it is obvious to combine the teaching of Atwood with Pan et al. to achieve the claimed invention. Therefore the rejection is maintained herein.

9. With regard to the rejection under 35 USC 103(a) as being obvious over Atwood in view of Kuan et al., Applicants’ arguments and amendment are fully considered and found unpersuasive. As discussed above Atwood does teach a predetermined volume and it is obvious to combine the teaching of Atwood with Kaun et al. to achieve the claimed invention. Therefore the rejection is maintained herein.

Conclusion

No claims are allowable.

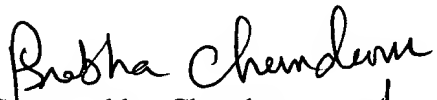
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Surya Prabha Chunduru
Patent Examiner
Art Unit 1637
10/17/05